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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/362,731	07/29/99	SAINT-REMY J	01699/P.UCB.

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EXAMINER	
HUYNH,P	
ART UNIT	**PAPER NUMBER**
1644	12

DATE MAILED: 04/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/362,731	SAINT-REMY ET AL.	
	Examiner	Art Unit	
	" Neon" Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-7, 9-12, and 15-17* is/are pending in the application.

4a) Of the above claim(s) *15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9-12 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

1. The instant application is complied with sequence rules for patent applications containing amino acid sequence disclosures.

2. Applicant's election with traverse of Group I, species Der pII of house dust mite *Dermatophagoides pteronyssinus* and Tetanus toxoid in Paper No. 11 is acknowledged. The traversal is on the grounds that the examiner has misinterpreted the scope of the claimed subject matter of Groups I and II. Group I is directed to a compound consisting of the B cell epitope of *Der pII* of house dust mite *Dermatophagoides pteronyssinus* and the T cell epitope of Tetanus toxoid. The subject of matter of Group II is directed to a compound consisting of an antibody to a B cell epitope and the T cell epitope. Furthermore, Group III and IV are directed to methods of treatment using different compounds. Upon further reconsideration, Group I and II encompass claims 1, 3-7, 9-12 and 17 directed to a compound consisting of B cell epitope and T cell epitope have been rejoined while Group III and IV encompass claims 15-16 directed to a method of treatment have also been rejoined. The requirement is still deemed proper and is therefore made FINAL.
   Claims 1, 3-7, 9-12, and 15-17 are pending.
   Claims 15-16 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to non-elected inventions.
   Claims 1, 3-7, 9-12 and 17 are being prosecuted in this Office Action.

3. Applicant is reminded that a claim for foreign priority under 35 U.S.C. § 119 (a-d), should **include a certified copy** of the foreign document filed in this application. However, none of the certified copy of the priority document have been received.

4. Applicant should amend the first line of the specification to indicate the status of the priority documents, i.e., This application claims Foreign Priority under 35 USC 119 (a-d) of EPO Application No. 98870167.8 filed 7/30/98. See MPEP 1302.04.

5. Applicant is reminded to update the list of power of attorney for practice before the office.

6. The drawings, filed 7/29/99, are not approved. Please see attached PTO 948. Appropriate correction is required.

7. Appropriate correction is required in the specification. See page 29 line 14 and page 29 line 14 "Sequence ID n°" should have been "sequence ID NO". SEQ ID NO: is required on page 25 line 30-31. "The use of single IgE-binding epitope has therefore be claimed" on page 3 line 29-30 should have been "The use of a single IgE-binding epitope has therefore been claimed". The phrase "aminoacid" on page 8 line 22, page 23 line 12 and throughout the specification should have been "amino acid". The phrase "Short description of the figures" on page 13 should have been "Brief Description of the Drawings". Furthermore, the brief description of the drawing on page 13 line 26 after "peptide 21" should indicate SEQ ID NOS. The phrase "Balb/c mice" on page 29 line 24, page 30 line 32 and throughout the specification should be "BALB/c mice" because "BALB/c" is the proper designation of this mouse strain. The phrase "Figure 1" on the abstract should be deleted.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 3-7, 9-12 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition in treating allergies in **mice** comprising a recombinant peptide consisting of a T cell epitope of tetanus toxoid or Influenza and a B cell epitope of *Der pII* or *Der pI* wherein the two epitopes are linked by two glycine residues (See page 22 line 25) does not reasonably provide enablement for a compound containing B cell epitope of the major **antigen of Aspergillus fumigatus, the staphylococcal B enterotoxin (SEB), the bovine β-lactoglobulin and T cell epitope of diphtheria, mycobacterium, or measles virus antigens** wherein the compound is used as a pharmaceutical composition, cosmetical composition, beverage, food and/or feed composition for **prevention or treating allergy to house dust mite in human**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The base claim 1 recites compound for the prevention and/or the treatment of allergy consisting of at least one allergen antigenic determinant which is recognized by a B cell **or an antibody secreted by a B cell of a non-atopic individual** and at least one antigenic determinant of an antigen different from said allergen which triggers T cell activation. The specification provides an example in which a compound consisting of 31 amino acids encoding by SEQ ID NO: 1 wherein the compound consisting of 15 amino acids of a T cell epitope of tetanus toxoid and a 14 amino acids of a B cell eipitope of *Der pII* dust mite joined together by two glycines (See Example 1, page 22-25). However, the specification fails to provide an enabling disclosure of a compound consisting of "antibody secreted by a B cell of a non-atopic individual" and a T cell epitope as recited in claim 1. Furthermore, the specification does not reasonably provide enablement for any compounds consisting of a B cell epitope from the major antigen of "Aspergillus fumigatus, the staphylococcal B enterotoxin (SEB)" and a T cell epitope from "diphtheria, mycobacterium, or measles virus antigens" for prevention and or treating allergy to said allergen other than *Der pII* antigen and T cell epitope of tetanus toxoid.

Regarding to a "pharmaceutical composition" and "medicament" as recited in claims 9 and 12, there are insufficient working examples and guidance in the specification as filed regarding the effective dose of a "pharmaceutical composition" for preventing and treating any allergy. A "pharmaceutical composition" comprising a "compound" for "treating" or "preventing" allergy to dust mite in the absence of in vivo data is unpredictable for the following reasons: (1) the protein may be inactivated before producing an effect, for instant, due to proteolytic degradation or immunological inactivation as a consequence of the inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO

Bd. Pat App. & Inter. 1992). Further, the specification fails to demonstrate whether said compound can **prevent allergy**, including dust mite, for example, measuring the IgE response of a subject (e.g. BALB/c mouse) upon challenge with Der pII. There is insufficient examples and guidance showing the efficacy of any compound in treating allergy. In the absence of demonstrating the ability of the test mice to withstand the challenge from exposure to Der pII, it would require undue experimentation for one skilled in the art to practice the claimed invention of "**prevent**" an allergic response in a subject, mouse or human.

Regarding to "cosmetic composition" and "beverage, food and/or feed composition" as recited in claims 10-11, the specification fails to provide enabling disclosure for said composition despite the specification provides a formulation for the claimed composition. Specifically, it is not clear as to the rationale for using a cosmetic composition for skin hygiene comprising the claimed anti-allergy compound. The specification also fails to demonstrate the efficacy of said anti-allergy compounds following topical or oral administration wherein the bioavailability of said compound in circulation has not been demonstrated.

In view of the insufficient number of working examples, the lack of guidance in the specification, the breath of the claims, and the unpredictable state of the art with respect to "preventing" and "treating" any allergy using any compound, it would require undue experimentation for one skilled in the art to practice the entire scope of the claimed invention.

Note, removing the phrase "prevention and/or treatment" and "or an antibody secreted by a B cell of a non-atopic individual" from claim 1, "pharmaceutical, cosmetic, beverage, food and/or feed composition" as recited in claims 9-12, "the major antigen of Aspergillus fumigatus, the staphylococcal B enterotoxin (SEB) and the bovine β-lactoglobulin as recited in claim 4 and "diphtheria, mycobacterium, or measles virus antigens as recited in claim 5 would overcome this rejection since one would know how to use a composition consisting of a B cell epitope of *Der pII* or *Der pI* and a T cell epitope of tetanus toxoid or influenza as screening assays as disclosed in the specification.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1, 4-5 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 1 recites "compound for the prevention and/or the treatment of allergy" consisting of "an antibody secreted by a B cell of a non-atopic individual to said allergen and at least one antigenic determinant of an antigen different from said allergen" as part of the invention. There is insufficient written description about "the prevention and/or the treatment of allergy" including the therapeutics effective dose, the efficacy of the compound and "the antibody secreted by a B cell of a non-atopic individual" linked to antigenic determinant of an antigen different from said allergen. The phrase "compound" is broad and the specification discloses recombinant peptides consisting of a B cell epitope of *Der pII* or *Der pI* and a T cell epitope of tetanus toxoid or influenza encoding by SEQ ID NOS: 1-5 as recited in claim 17. Further, none of the compounds consisting of "the major antigen of Aspergillus fumigatus, the staphylococcal B enterotoxin (SEB) and the bovine β-lactoglobulin as recited in claim 4 and "diphtheria, mycobacterium, or measles virus antigens as recited in claim 5 are described in the specification including "an antibody secreted by a B cell of a non-atopic individual" to said allergen as recited in claim 1 meet the written description provision of 35 U.S.C. 112, first paragraph. In re Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, it is clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

In view of the inadequate written description that support "*compound for the prevention and/or the treatment of allergy*" consisting of at least one allergen antigenic determinant which is recognized by a B cell *"or an antibody secreted by a B cell of non-atopic individual"* or "*the major antigen of Aspergillus fumigatus, the staphylococcal B enterotoxin (SEB) and the bovine β-lactoglobulin*" as recited in claim 4 *and "diphtheria, mycobacterium, or measles virus antigens"* as recited in claim 5, one skilled artisan can envision neither all the contemplated "*compound*" in preventing nor treating a subject with said compound. Consequently, conception in either case cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that

it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. In re Fiddes v. Baird, 30 USPQ2d 1481, 1483. In re Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999. Alternatively, Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as filed.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1, 3-7, 9-12 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "compound" as recited in claims 1 and dependent claims 3-7, 9-12 and 17 is being indefinite because the term is ambiguous as to the metes and bounds of the claims compound. The claim as written, reads on natural compounds. Also, an article "A" or "The" is required.

The phrase "and/or" as recited in claims 1 and 11 and dependent claims 3-7, 9-10, 12 and 17 is being indefinite because "and/or" is not appropriate in the claims. It is suggested that applicants amend the claims to recite either "and" or "or".

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1, 3-7, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bixler *et al.* (US Patent No 5,785,973, see entire document).

Bixler et al teach compounds and pharmaceutical compositions for prevention and/or treatment of allergy consisting of at least one allergen antigenic determinant which is recognized by a B cell and at least one antigenic determinant of an antigen different from said allergen which triggers T cell activation (See entire document, summary of the Invention; column 8 line 35- 51; column 29 line 65 bridging column 31 in particular). The T cell epitope includes tetanus toxoid, diphtheria and influenza (See column 10, source of T cell epitopes; column 12, line 25; column 19 line 1; column 21, line 24; column 33 line 20 in particular) while the B cell epitope of antigenic determinant includes allergens such as house dust mite *Dermatophagoides pteronyssinus*, ragweed, rye grass and staphylococcal B enterotoxin (See column 12, line 51-64). Furthermore, the antigenic determinants of the B and T cell epitopes are bound together by a peptide linker wherein the linker is glycine (See column 14 line 9, claims 18-19 in particular).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced sequences.

Applicant is reminded that the term "compound" without reciting the specific SEQ ID NOS expands the scope of the claimed nucleic acid molecules.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

18. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

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April 19, 2001

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